Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

# General

## Guideline Title

Magnetic resonance imaging for breast cancer screening, pre-operative assessment, and follow-up.

## Bibliographic Source(s)

Alberta Provincial Breast Tumour Team. Magnetic resonance imaging for breast cancer screening, pre-operative assessment, and follow-up. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2012 Jan. 19 p. (Clinical practice guideline; no. BR-007). [52 references]

## Guideline Status

This is the current release of the guideline.

This guideline was republished in 2012 following an ad hoc review by members of the Alberta Provincial Breast Tumor Team that resulted in a minor change.

# Recommendations

## Major Recommendations

Screening

Mammography is the recommended modality for screening breast cancer in the general population of asymptomatic women (Perry et al., 2008; Mandelblatt et al., 2009).

- The Alberta Breast Cancer Screening Program (Alberta Breast Cancer Screening Program, 2009), recommends:
  - Encouraging eligible women age 50 to 69 to have a screening mammogram every two years,
  - Advising them of their results, and
  - Reminding them if they are overdue for a repeat screening.
  - Women aged 40-49 and over 70 may be referred to the Program by a family physician.

Magnetic resonance imaging (MRI) should be used in addition to mammography, at an interval of every 12 months, for screening high-risk category patients; these include women who (National Comprehensive Cancer Network [NCCN], "Invasive," 2009; NCCN, "Breast cancer," 2009; National Collaborating Centre for Primary Care, 2006; Morris et al., 2008):

- Have known personal history of deleterious mutation(s) in either BRCA1, BRCA2, TP53 or PTEN
- Have never been tested personally but have a first degree relative with known BRCA1, BRCA2, TP53 or PTEN
- Have a personal lifetime risk of developing breast cancer of 20-25 percent or more according to models that are largely dependent on family history

- Are under 50 years of age and have received radiation treatment to the chest between ages 10 and 30 (e.g., thoracic radiation therapy for Hodgkin's disease)
  A more detailed guideline, Risk Reduction and Surveillance Strategies for Individuals at High Genetic Risk for Breast and Ovarian Cancer, developed by Alberta Health Services in 2007 and revised in 2011, is available at the following website: http://www.albertahealthservices.ca/hp/if-hp-cancer-guide-br011-hereditary-risk-reduction.pdf.

There is *insufficient* evidence to recommend routine use of MRI screening in women who (Myers et al., 2006; Saslow et al., 2007; Morris et al., 2008):

- Have a lifetime risk of breast cancer of 15-20 percent, as defined by models that are largely dependent on family history
- Have only had lobular carcinoma in situ (LCIS) or atypical lobular hyperplasia (ALH)
- Have only had atypical ductal hyperplasia (ADH)
- Have heterogeneously or extremely dense breasts on mammography with no other risk features
- Have personal history of breast cancer, but do not otherwise fit into the high-risk category as noted above

Pre-operative Assessment

Pre-operative MRI may be considered in the following circumstances:

- Biopsy proven axillary nodal adenocarcinoma with no primary identified on mammography, ultrasound, and physical examination.
- Discordant clinical and mammogram/ultrasound findings.

Pre-operative MRI may be used in the following situations where the patient desires breast conserving surgery and (NCCN, "Invasive," 2009; NCCN, "Breast cancer," 2009; Calgary Health Region High Risk Breast Cancer Interest Group, 2008):

- There is high risk for multifocal/multicentric disease.
- The extent of disease is unclear.

MRI may be used for breast cancer evaluation before, during and after neoadjuvant therapy to help evaluate response to systemic treatments (Yuan et al., 2010; Bistritz, 2010).

- MRI may overestimate response to neoadjuvant chemotherapy and should not be used to plan post-chemotherapy breast conserving surgery.
- MRI accurately predicts lack of response to neoadjuvant chemotherapy and may be used to support a change in therapy.

Problem Solving

MRI may be considered only after high quality mammogram and ultrasound have been carried out and the results are inconclusive or discordant. MRI should not be used in lieu of biopsy if more appropriate or in cases where clinical and radiological suspicion is low.

MRI is not recommended for the routine screening of patients with nipple discharge.

Follow-up

The following recommendation has been adapted from the National Comprehensive Cancer Network (NCCN, "Invasive," 2009; NCCN, "Breast cancer," 2009).

There is *insufficient* evidence to recommend MRI for follow-up screening of the ipsilateral and contralateral breast of women with prior breast cancer unless they are in the high-risk category, as per the recommendations in the section on *Screening*.

Operational Considerations

The following recommendations have been adapted from the National Comprehensive Cancer Network (NCCN, "Invasive," 2009; NCCN, "Breast cancer," 2009).

Breast MRI examinations require a dedicated breast coil and breast imaging radiologists familiar with the optimal timing sequences and other technical details for image interpretation.

Breast MRI examinations should be performed and interpreted by an experienced radiologist with training in breast MRI, working in concert with the multidisciplinary treatment team.

Patients meeting the criteria for MRI should be referred to a centre with an MRI machine that has been configured with a dedicated breast coil.

### Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Breast cancer

### Guideline Category

Diagnosis

Evaluation

Screening

Technology Assessment

### Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Oncology

Radiology

Surgery

### Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

### Guideline Objective(s)

To develop a consensus based guideline, structured on evidence from existing practice guidelines, for using magnetic resonance imaging (MRI) within the context of breast cancer

## Target Population

All women eligible for breast cancer screening or who have had breast cancer

## Interventions and Practices Considered

1. Mammography
2. Breast magnetic resonance imaging (MRI)
3. Facility/staff requirements for breast MRIs

## Major Outcomes Considered

- Sensitivity and specificity of breast magnetic resonance imaging (MRI)
- Cost-effectiveness of MRI

# Methodology

## Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Research Questions

Specific research questions to be addressed by the guideline document were formulated by the guideline lead(s) and Knowledge Management (KM) Specialist using the PICO question format (patient or population, intervention, comparisons, outcomes).

Guideline Questions

1. Should magnetic resonance imaging (MRI) be used for breast cancer screening?
2. Should MRI be used for preoperative assessment of breast cancer?
3. Should MRI be used for the follow up of patients treated for breast cancer?
4. In which patients is the use of MRI appropriate?
5. Are there other considerations?

Search Strategy

A systematic search for relevant, existing practice guidelines, systematic reviews, health technology assessments, meta-analyses, and randomized controlled trials was conducted of: MEDLINE, CINAHL, EMBASE, CancerLit, the Cochrane Library, and the National Guideline Clearinghouse.

The search terms included "breast neoplasm" and "magnetic resonance imaging." The search covered the period between 1965 and July 2010. A total of 95 articles were returned. The majority were review articles; there were seven clinical trials, nine meta-analyses, 12 comparative studies, and nine guidelines.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Not stated

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Breast Tumour Team and a Knowledge Management (KM) Specialist from the Guideline Utilization Resource Unit (GURU). A detailed description of the methodology followed during the guideline development process can be found in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field).

Evidence Tables

Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest are assembled using the studies identified in the literature search. Existing guidelines on the topic are assessed by the KM Specialist using portions of the AGREE II instrument (http://www.agreetrust.org) and those meeting the minimum requirements are included in the evidence document. Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Formulating Recommendations

The working group members formulated the guideline recommendations based on the evidence synthesized by the Knowledge Management (KM) Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field), the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members is explicitly stated in the guideline recommendations. Similar to the American Society of Clinical Oncology (ASCO) methodology for formulating guideline recommendations, the Guideline Utilization Resource Unit (GURU) does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.

There was a paucity of data on many of the uses of magnetic resonance imaging (MRI) in the context of breast cancer. As such, the guideline developers have chosen to make provincial recommendations for use of MRI, by adapting from existing evidence-informed guidelines elsewhere. A recommendations matrix highlighting key guidance from nine existing guidelines on the use of MRI for breast cancer assessment, staging, and follow-up, is included in the Appendix of the original guideline document.

## Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

The large COMICE trial out of the UK showed that in women with biopsy-proven primary breast cancer who had undergone conventional assessment followed by magnetic resonance imaging (MRI) (1.5 T or 1.0 T) with a dedicated bilateral breast coil (n=816), the re-excision rates were similar (odds ratio = 0.96, 95% CI 0.75-1.24, p=0.7691) to those of women who had not undergone MRI (n=807) and there were no significant differences in the proportion of patients receiving chemotherapy, radiotherapy or additional adjuvant therapies, local recurrence-free interval rates, quality of life measures, or economics. As such, the use of MRI in this setting may be limited in cost-effectiveness. However, preoperative biopsy of MRI-only-detected lesions (i.e., occult breast cancer) could minimize the incidence of inappropriate mastectomy, as MRI has been shown to provide the possibility of breast conserving surgery in as many as a third of patients with occult breast cancer. Furthermore, MRI may be cost-effective in patients with invasive lobular carcinoma, in which a sensitivity of MRI of 93.3% has been demonstrated and resulted in a change in surgical management in 28.3% of cases. More research is needed in order to identify the subtypes of breast cancer patients that may benefit most from MRI assessment, thereby maximizing the cost-effectiveness of this application.

Within Alberta Health Services, Cancer Care, access to MRI machines configured with a dedicated breast coil may be limited to the larger urban centres. As such, patients presenting with indications for breast MRI, as outlined in the recommendations section, may require a referral to a larger centre if an MRI machine capable of imaging the breast is not available locally or if local expertise in breast MRI is limited. The cost of a typical MRI scan in 2004/2005 in Alberta was approximately $500. The number of additional MRI scans, as a result of this guideline, is expected to be minimal. In 2011, there are expected to be 2,090 new diagnoses of breast cancer. Assuming conservatively that up to 15% of new breast cancer cases require MRI for the purposes of problem solving or pre-operative assessment, and that 1% of the population of women in Alberta fall into the high-risk category, an estimated 330 breast MRI scans will be performed annually, as a result of this guideline. This would result in a total cost per year of $165,000. Other possible costs would include staffing and travel expenses for remote patients.

## Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

This guideline was reviewed and endorsed by the Alberta Provincial Breast Tumour Team.

When the draft guideline document is completed, revised, and reviewed by the Knowledge Management Specialist and the working group members, it will be sent to all members of the Provincial Tumour Team for review and comment. The working group members will then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it will be officially endorsed by the Provincial Tumour Team Lead and the Director of Provincial Clinical Teams.

# Evidence Supporting the Recommendations

## References Supporting the Recommendations


Alberta Breast Cancer Screening Program. Types of mammograms: screening mammograms. [internet]. Edmonton (Alberta): Alberta Health Services; [accessed 2009 Oct 09].

Bistritz A. Personal communication. 2010 Jul 23.

Calgary Health Region High Risk Breast Cancer Interest Group. Practice guideline report 1.0. Edmonton (Alberta): Alberta Health Services; 2008 Apr 1.

Mandelblatt JS, Cronin KA, Bailey S, Berry DA, de Koning HJ, Draisma G, Huang H, Lee SJ, Munsell M, Plevritis SK, Ravdin P, Schechter CB, Sigal B, Stoto MA, Stout NK, van Ravesteyn NT, Venier J, Zelen M, Feuer EJ, Breast Cancer Working Group of the Cancer Intervention and Surveillance Modeling. Effects of mammography screening under different screening schedules: model estimates of potential benefits and harms. Ann Intern Med. 2009 Nov 17;151(10):738-47. PubMed

Morris EA, Bassett LW, Berg WA, Birdwell RL, Brenner RJ, Comstock CE, DeBruhl ND, D'Orsi CJ, Evans WP III, Everson LI, Harvey JA, Herman CR, Jong RA, Kaplan SS, Liberman L, Mahoney MC, Mendelson EB, Parikh JR, Rabinovitch RA, et al. ACR practice guideline for the performance of contrast-enhanced magnetic resonance imaging (MRI) of the breast. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 7 p. [44 references]

Myers R, Minuk T, Johnston M, Diagnostic Imaging Guidelines Panel. Diagnostic imaging in breast cancer: recommendations report. Toronto (ON): Cancer Care Ontario (CCO); 2006 Apr 12. 19 p. [18 references]

National Collaborating Centre for Primary Care. Familial breast cancer. The classification and care of women at risk of familial breast cancer in primary, secondary and tertiary care. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Oct. 50 p. (Clinical guideline; no. 41).

National Comprehensive Cancer Network (NCCN). Breast cancer screening and diagnosis: practice guidelines in oncology, v.2.2009. Fort Washington (PA): National Comprehensive Cancer Network (NCCN); 2009.

National Comprehensive Cancer Network (NCCN). Invasive breast cancer: practice guidelines in oncology, v.1.2009. Fort Washington (PA): National Comprehensive Cancer Network (NCCN); 2009.

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Yuan Y, Chen XS, Liu SY, Shen KW. Accuracy of MRI in prediction of pathologic complete remission in breast cancer after preoperative therapy: a meta-analysis. AJR Am J Roentgenol. 2010 Jul;195(1):260-8. PubMed

### Type of Evidence Supporting the Recommendations

The recommendations were adapted from existing evidence-informed guidelines.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate use of magnetic resonance imaging (MRI) for breast cancer screening, pre-operative assessment, and follow-up

### Potential Harms

False positive results from magnetic resonance imaging (MRI)

# Contraindications

## Contraindications

Contrast enhanced magnetic resonance imaging (MRI), using gadolinium-based contrast agent, is contraindicated during pregnancy, as there are no adequate and well-controlled studies of its use in pregnant women. However, in rare and extenuating circumstances, whereby the health of the mother and/or fetus would be significantly compromised without a contrast enhanced MRI, and after all other imaging options (i.e., ultrasound, computed tomography [CT], nuclear scintigraphy, fluoroscopy, etc.) have been exhausted, MRI with a gadolinium-based contrast agent could be considered. Patients should be informed of the risks and benefits of the procedure.

# Qualifying Statements

## Qualifying Statements

The recommendations contained in this guideline are a consensus of the Alberta Provincial Breast Tumour Team and represent a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.

# Implementation of the Guideline

## Description of Implementation Strategy

- Present the guideline at the local and provincial tumour team meetings and weekly rounds.
- Post the guideline on the Alberta Health Services website.
- Send an electronic notification of the new guideline to all members of Alberta Health Services, Cancer Care.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

Staying Healthy

## IOM Domain

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

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## Adaptation

The recommendations in this guideline were adapted from the following guidelines:

- National Comprehensive Cancer Network. Invasive Breast Cancer: Practice Guidelines in Oncology, v.1.2009.
- National Comprehensive Cancer Network. Breast Cancer Screening and Diagnosis: Practice Guidelines in Oncology, v.2.2009.

## Date Released

2010 Oct (republished 2012 Jan)

## Guideline Developer(s)

CancerControl Alberta - State/Local Government Agency [Non-U.S.]

## Source(s) of Funding

Alberta Health Services, Cancer Care

## Guideline Committee

Magnetic Resonance Imaging for Breast Cancer Working Group

## Composition of Group That Authored the Guideline

Not stated

## Financial Disclosures/Conflicts of Interest

Participation of members of the Alberta Provincial Breast Tumour Team in the development of this guideline has been voluntary and the authors have not been remunerated for their contributions. There was no direct industry involvement in the development or dissemination of this guideline. Alberta Health Services, Cancer Care recognizes that although industry support of research, education and other areas is necessary in order to advance patient care, such support may lead to potential conflicts of interest. Some members of the Alberta Provincial Breast Tumour Team are involved in research funded by industry or have other such potential conflicts of interest. However the developers of this guideline are satisfied it was developed in an unbiased manner.

## Guideline Status

This is the current release of the guideline.

This guideline was republished in 2012 following an ad hoc review by members of the Alberta Provincial Breast Tumor Team that resulted in a minor change.

## Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

## Availability of Companion Documents

The following is available:

- Guideline utilization resource unit handbook. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2011 Dec. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on February 28, 2012. The information was verified by the guideline developer on March 30, 2012.

## Copyright Statement



# Disclaimer

## NGC Disclaimer